UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

SHARON L. HERDA	§	
	§	
Plaintiff,	§	
	§	
	§	**Case No. 1:08 GD 50000**
	§	
v.	§	**MDL No. 1909**
	§	
	§	**MDL Case No. _____**
BAYER CORPORATION; BAYER	§	
HEALTHCARE LLC; BAYER	§	**Judge Dan Aaron Polster**
PHARMACEUTICALS CORPORATION;	§	
BAYER HEALTHCARE	§	
PHARMACEUTICALS, INC.; BERLEX	§	
LABRATORIES, INC.; BERLEX, INC.;	§	
BAYER SCHERING PHARMA AG;	§	
BAYER AG; BRACCO DIAGNOSTICS	§	
INC.; BRACCO RESEARCH USA, INC.;	§	
ALTANA PHARMA AG; NYCOMED	§	
INTERANTIONAL MANAGEMANT	§	
GMBH; GENERAL ELECTRIC	§	
COMPANY; GE HEALTHCARE, INC.;	§	
GE HEALTHCARE BIO-SCIENCES	§	
CORP.; GE HEALTHCARE AS; TYCO	§	
INTERNATIONAL, LTD.; TYCO	§	
HEALTHCARE, LTD.; TYCO	§	
INTERNATIONAL (US) INC.; TYCO	§	
HEALTHCARE GROUP, LP.; COVIDIEN,	§	
LTD.; MALLINCKRODT, INC.;	§	
	§	
	§	
Defendants.	§	

IN RE: GADOLINIUM BASED CONTRAST AGENTS PRODUCTS LIABILITY LITIGATION

COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

Plaintiff Sharon L. Herda, by and through her attorneys, Beasley, Allen, Crow, Methvin, Portis, & Miles, P.C. and for her Complaint and Jury Demand against Defendants, alleges as follows:

FILING OF CAUSE OF ACTION IN MULTIDISTRICT LITIGATION

The parties to this cause are of diverse citizenship, as set forth in the following section of this Complaint. Thus, jurisdiction is appropriate in the United States District Court, pursuant to 28 U.S.C. § 1332. This cause of action could have been brought in the federal district court in Wisconsin but is being brought in this Multidistrict Litigation by direct filing pursuant to Pretrial Order No. 1 and Case Management Order No. 3, entered by the Honorable Dan Aaron Polster, United States District Judge for the Northern District of Ohio – Eastern Division. Plaintiff Sharon L. Herda consents to the jurisdiction of the MDL court to the extent set forth in Pretrial Order No.1 and Case Management Order No. 3.

PARTIES, VENUE AND JURISDICTION

1. Plaintiff Sharon L. Herda is a resident and citizen of Adams County, Wisconsin.

2. Defendant Bayer Corporation is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205. Said defendant performs business in the State of Wisconsin and in Adams County.

3. Defendant Bayer Healthcare LLC, is, and at all times relevant was a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205. Said defendant performs business in the State of Wisconsin and in Adams County.

4. Defendant Bayer Pharmaceuticals Corporation is, and at all times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut. Said defendant performs business in the State of Wisconsin and in Adams County.

5. Defendant Bayer Healthcare Pharmaceuticals, Inc. (formerly known as Berlex Laboratories Inc. and/or Berlex, Inc.) is, and at all times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 6 West Belt, Wayne, New Jersey. Bayer Healthcare Pharmaceuticals, Inc. is a division of Bayer AG. Said defendant performs business in the State of Wisconsin and in Adams County.

6. Defendants Berlex Laboratories, Inc. and Berlex, Inc. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of PO Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey, 07470. Said defendants perform business in the State of Wisconsin and in Adams County.

7. Defendant Bayer Schering Pharma AG, was at all times relevant a German Corporation. Bayer Schering Pharma AG is a corporate successor to Schering AG. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006. Its headquarters and principal place of business in the United States are located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205. Said defendant performs business in the State of Wisconsin and in Adams County.

8. Defendant Bayer AG is, and at all times relevant was, a German corporation and is the parent/holding company of all other Bayer Defendants. Its headquarters and principal place of business in the United States are located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205. Said defendant performs business in the State of Wisconsin and in Adams County.

9. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc., Berlex, Inc., Bayer Schering Pharma AG, and Bayer AG shall be referred to herein individually by name or jointly as "Bayer".

10. Bayer designed, manufactured and marketed a gadolinium-based contrast agent by the name of Magnevist. Said product was sold, distributed and marketed throughout the United States, including the State of Wisconsin.

11. Defendant Bracco Diagnostics Inc. is, and at all times relevant was, a corporation organized under the laws of the State of Delaware with its principal place of business at 107 College Road East, Princeton, New Jersey, 08450. Said defendant performs business in the State of Wisconsin and in Adams County.

12. Defendant Bracco Research USA, Inc., is, and at all times relevant was, a corporation organized under the laws of the State of Delaware with its principal place of business at 305 College Road East, Princeton, New Jersey, 08450. Said defendant performs business in the State of Wisconsin and in Adams County.

13. Defendant ALTANA Pharma AG, is, and at all times relevant was, a German company with its principal place of business located at 45 Abelstrae, Wesel, Germany 46483. Said defendant performs business in the State of Wisconsin and in Adams

County. Defendant ALTANA Pharma AG manufactured gadolinium-based contrast agents by the name of "Multihance" and "Prohance" for Bracco Diagnostics, Inc.

14. Defendant Nycomed International Management GMBH, is, and at all times relevant hereto was, a Swiss company with its principal place of business located at Leutschenbachstr 95, Zurich, Switzerland, CH-8050 and with its principal place of business in the United States located at 60 Baylis Road, Melville, New York, 11747. Said defendant performs business in the State of Wisconsin and in Adams County. Defendant Nycomed International Management GMBH bought ALTANA Pharma in 2006. Defendant Nycomed International Management GMBH is the corporate successor to ALTANA Pharma AG.

15. Defendants Bracco Diagnostics Inc., Bracco Research USA, Inc., ALTANA Pharma AG, and Nycomed International Management GMBH shall be referred to hereinafter individually by the name or collectively as "Bracco".

16. Bracco Diagnostics Inc., Bracco Research USA, Inc., ALTANA Pharma AG, and Nycomed International Management CMBH developed, manufactured and marketed gadolinium contrast agents by the names of "Multihance" and "Prohance" for sale in Adams County, Wisconsin and in other locations.

17. Defendant General Electric Company is, and at all times relevant was, a corporation organized under the laws of the State of New York, with a principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut, 06431. Defendant General Electric Company is a resident and citizen of both New York and Connecticut. Said defendant performs business in the State of Wisconsin and in Adams County. Defendant

General Electric Company is the parent company of Defendant GE Healthcare, Inc., GE Healthcare AS, and Defendant GE Healthcare Bio-Science Corp.

18. Defendant GE Healthcare, Inc. is, and at all times relevant was, a corporation organized under the laws of the State of Delaware with its principal place of business at 101 Carnegie Center, Princeton, New Jersey. Defendant GE Healthcare, Inc. is a resident and citizen of both Delaware and New Jersey. Said defendant performs business in the State of Wisconsin and in Adams County. Defendant GE Healthcare, Inc. is a subsidiary of General Electric Company.

19. Defendant GE Healthcare Bio-Sciences Corp. is, and at all times relevant was, a corporation organized under the laws of the State of Delaware with its principal place of business at 800 Centennial Avenue, Piscataway, New Jersey, 08854. Defendant GE Healthcare Bio-Sciences Corp. is a subsidiary of General Electric Company.

20. Defendant GE Healthcare AS is, and at all times relevant was a corporation organized in the Kingdom of Norway with its principal place of business located at 4220 Nydalen, Olso, Norway, 0401. Said defendant performs business in the State of Wisconsin and in Adams County. Defendant GE Healthcare AS is a subsidiary of General Electric Company.

21. At all times relevant, Defendants General Electric Company, GE Healthcare, Inc., GE Healthcare Bio-Sciences Corp., and GE Healthcare AS, shall be referred to herein collectively as "GE". GE developed, manufactured and marketed a gadolinium-based contrast agent by the name "Omniscan" for sale and use in the Adams County, Wisconsin and in other locations.

22. Defendant Tyco International, Ltd., is, and at all times relevant was, a corporation organized under the laws of Bermuda and the address of its corporate office and principal place of business is 90 Pitts Bay Road, 2nd Floor, Pembroke HM 08, Bermuda and has its United States operational headquarters (Tyco International (US) Inc.) at 9 Roszel Road, Princeton, New Jersey 08450. Said defendant performs business in the State of Wisconsin and in Adams County.

23. Defendant Tyco Healthcare Ltd. is, and at all times relevant was, a corporation organized under the laws of Bermuda and has its United States Headquarters at 15 Hampshire Street, Mansfield, Massachusetts 02048. Said defendant performs business in the State of Wisconsin and in Adams County.

24. Defendant Tyco International (US) Inc. is, and at all times relevant was, a foreign corporation with its principal place of business at 9 Roszel Road, Princeton, New Jersey 08450. Said defendant performs business in the State of Wisconsin and in Adams County.

25. Defendant Tyco Healthcare Group, LP is, and at all times relevant was, a limited partnership organized under the laws of the State of Delaware having its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048. Said defendant performs business in the State of Wisconsin and in Adams County.

26. Defendant Covidien Ltd., formerly Tyco Healthcare, is, and at all times relevant was, a Bermuda corporation with its United States headquarters at 15 Hampshire Street, Mansfield, Massachusetts 02048. It became a successor-in-interest to Tyco Healthcare Ltd. and Tyco Healthcare Group LP as of June 29, 2007. Said defendant performs business in the State of Wisconsin and in Adams County.

27. Defendant Mallinckrodt, Inc. is, and at all times relevant was, a corporation organized under the laws of the State of Delaware with its principal place of business at 675 McDonnel Blvd., St. Louis, Missouri. Defendant Mallincrokdt, Inc., is a resident and citizen of both Delaware and Missouri. Said defendant performs business in the State of Wisconsin and in Adams County. Defendant Mallinckrodt, Inc., is a subsidiary of Tyco Healthcare Group LP.

28. Defendants Tyco International Ltd., Tyco Healthcare Ltd., Tyco International (US), and Tyco Healthcare Group, LP, Inc. are corporate divisions, subsidiaries, or limited partners, or otherwise operate under the corporate umbrella of Tyco International Ltd, and shall be referred to hereinafter individually by name or collectively as "Tyco".

29. Defendants Tyco, Covidein, Ltd., and Mallinckrodt, Inc. developed, marketed and manufactured a gadolinium-based contrast agent by the name of "OptiMark" for sale and use in Adams County, Wisconsin and other locations.

30. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and were at all time operating and acting with the purpose and scope of said agency, service, employment partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other Defendants knowing that the conduct constituted a breach of duty.

31. Defendants are subject to personal jurisdiction of this Court as a result of their doing business within the State of Wisconsin, have systematic and continuous contacts with the State of Wisconsin, have consented jurisdiction of the State of Wisconsin.

FACTUAL BACKGROUND

32. Defendants designed, manufactured and marketed the gadolinium-based contrast agents: Magnevist, Multihance, Prohance, Omniscan and Optimark for sale. These solutions are injectable paramagnetic contrast agents for magnetic resonance imaging (MRI). These contrast agents contain the metal gadolinium which is highly toxic in its free state. Defendants represented these contrast agents as safe and effective for intravenous administration to facilitate the visualization of lesions or malformation with abnormal vascularity.

33. These contrast agents are cleared from the body by glomerular filtration in the kidneys. As a result, it has prolonged half-life in patients with renal insufficiency and who, therefore, are at increased risk for adverse health effects in connection with gadolinium-based contrast agents administration.

34. In pre-clinical safety assessment during which gadolinium-based contrast agents were injected into laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the skin and other body organs occurred.

35. Despite these nephrogenic fibrotic changes and other data warranting caution and further evaluation, gadolinium-based contrast agents, Defendants marketed and sold the gadolinium-based contrast agents without appropriate clinical evaluation of the nephrotoxic effect of the drugs on patients with renal insufficiency, without appropriate clinical evaluation of the propensity of this agents to produce nephrogenic fibrosis in humans, and without appropriate and effective warning with respect to either.

36. At all times relevant hereto, Defendants knew or should have known about the significant health risk of gadolinium-based contrast agent administration to patients with

renal insufficiency, including but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs.

37. Nephrogenic Systemic Fibrosis (NSF), also known as Nephrogenic Fibrosing Dermopathy (NFD), has been reported in medical literature for at least the last decade.

38. Prior to a decade ago, the group of symptoms now known as NSF/NFD had been variously described as scleromyxedema, scleroderma, or other connective tissue diseases. The clinical entity now known as NSF/NFD develops only in patients with renal insufficiencies that have been given an injection of gadolinium-type contrast agents.

39. While there are gadolinium-based contrast agents available for administration in the United States, greater than 90% of all patients who have been diagnosed with NSF/NFD have received injections of gadolinium-based contrast agents in connection with magnetic resonance imaging.

40. NSF/NFD is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin within days or weeks after receiving a gadolinium-based contrast agent injection. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF/NFD often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching or severe pain in the areas involvement. NSF/NFD also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver and musculature, and that can inhibit their ability to function properly and may lead to death. NSF/NFD is a progressive disease as to which is no known cure.

41. The Defendants have consistently failed to warn consumers and/or their health care providers that NSF/NFD could result when gadolinium-based contrast agents are administered to patients with renal insufficiency.

42. During the years that Defendants manufactured, marketed and sold gadolinium-based contrast agents there have been numerous case reports, studies, assessments, papers and other clinical data that have described and/or demonstrated NSF/NFD in connection with the use of gadolinium-based contrast agents. Despite this, Defendants have repeatedly failed to revise their package inserts and product literature in order to convey adequate warnings.

43. In June 2006, and again in updated form in December 2006, the FDA issued Public Health Advisory Alerts concerning the development of serious, sometimes fatal, NSF/NFD following exposure to gadolinium-based contrast agents.

44. The Defendants have repeatedly and consistently failed to advise consumers and/or their health care providers of the causal relationship between gadolinium-based contrast agents and NSF/NFD in patients with renal insufficiency.

45. The Defendants have failed to take prompt, reasonable, and effective measures to alert the appropriate members of the health care community and its patients, including, but not limited to, renal patients, nephrologists and other physicians, radiologists, to the serious adverse health risks presented by administration of gadolinium-based contrast agents.

46. Prior to August 2005, Defendants knew or should have known that the administration of gadolinium-based contrast agent to patients with renal insufficiency created an increased risk to those consumers of serious personal injury and even death.

47. Defendants knew or should have known that the use of gadolinium-based contrast agents created an increased risk of serious personal injury or even death to consumers with renal insufficiency.

48. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of gadolinium-based contrast agents, Defendants failed to inform the healthcare community and end users, including Plaintiff Sharon L. Herda, of those serious risks.

49. Had Plaintiff Sharon L. Herda and/or her health care providers known the risks of damages associated with gadolinium-based contrast agents, Plaintiff Sharon L. Herda would not have been administered gadolinium-based contrast agents and would not have been afflicted with NSF/NFD or other serious injuries.

50. As a direct and proximate result of Plaintiff Sharon L. Herda being administered gadolinium-based contrast agents, she has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, including, but not limited to, suffering from NSF/NFD, which may have caused permanent effects, and which may continue in the future to cause their physical effects and damage which will affect her throughout her lifetime and may lead to an early or untimely death.

51. Further, as a direct and proximate result of Plaintiff Sharon L. Herda being administered gadolinium-based contrast agents, she has suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

52. Plaintiff Sharon L. Herda has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate

result of her being administered gadolinium-based contrast agents.

PLAINTIFF – SHARON L. HERDA

53. As a result of Defendants' claim regarding the safety and effectiveness of gadolinium-based contrast agents, Plaintiff Sharon L. Herda, in the course of receiving a medical evaluation by her doctor, was administered gadolinium-based contrast agents manufactured by the Defendants and has now developed NSF/NFD, symptoms consistent therewith or other serious and complicated health issues.

54. Neither Plaintiff Sharon L. Herda, her prescribing physicians, nor the performing radiologists or technicians were adequately warned or cautioned by Defendants about the serious health risks presented by the administration of gadolinium-based contrast agents.

55. As a direct and proximate result of being administered gadolinium-based contrast agent, Plaintiff Sharon L. Herda has suffered serious, progressive, incurable, and potentially fatal injuries.

COUNT I
STRICT PRODUCTS LIABILTY –
MANUFACTURING DEFECT

56. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

57. Defendants are the manufactures, designers, distributors, sellers, or suppliers of the gadolinium-based contrast agents.

58. The gadolinium-based contrast agents manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective by design, manufacture, construction and application when the agents left the hands of the

Defendants, and the agents deviated from product specifications, posing a serious risk of injury and death.

59. As a direct and proximate result of Plaintiff Sharon L. Herda being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Sharon L. Herda has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory and punitive damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT II
STRICT PRODUCTS LIABILTY – DEFECT DUE TO INADEQUATE WARNING

60. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

61. The gadolinium-based contrast agents manufactured and supplied by Defendants were defective due to inadequate warnings or instructions to healthcare professionals, end users, and the general public. Defendants knew or should have known that gadolinium-based contrast agents created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks. Further, the gadolinium-based contrast agents manufactured and supplied by Defendants were used in a manner reasonably anticipated by the Defendants.

62. The gadolinium-based contrast agents manufactured and supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm and death from the administration of gadolinium-based contrast agents, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the products, knowing the product could cause serious injury and death. To the extent that the Defendants provided instructions or warnings to consumers and/or their healthcare professionals, those instructions and warnings were inadequate, incomplete, fraudulent, and erroneous.

63. As a direct and proximate result of Plaintiff Sharon L. Herda being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff Sharon L. Herda has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory and punitive damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT III
STRICT PRODUCTS LIABILTY – DEFECT DUE TO NON CONFORMANCE WITH REPRESENTATIONS

64. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

65. Defendants are the manufacturers, designers, distributors, sellers or suppliers of gadolinium-based contrast agents and made representations regarding the character or quality of the gadolinium-based contrast agents, including representations that gadolinium-based contrast agents were safe.

66. The gadolinium-based contrast agents manufactured and supplied by the Defendants were defective in that, when they left the hands of the Defendants, they did not conform to representations made by Defendants concerning the products.

67. Plaintiff Sharon L. Herda and/or her health care providers who prescribed and administered the gadolinium-based contrast agents justifiably relied upon Defendants' representations regarding the gadolinium-based contrast agents at the time they were administered to her.

68. As a direct proximate result of Plaintiff Sharon L. Herda being administered gadolinium-based contrast agents and the reliance on Defendants' representations regarding the character and quality of gadolinium-based contrast agents, Plaintiff Sharon L. Herda suffered serious physical injury, harm, damages and economic loss and will continue to suffer harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory and punitive damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT IV
STRICT PRODUCTS LIABILTY –
DEFECT DUE TO FAILURE TO ADEQUATELY TEST

69. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

70. Defendants advised and informed consumers and the medical community that gadolinium-based contrast agents were safe for use. Defendants failed to adequately test the gadolinium-based contrast agents with respect to their use by consumers with renal insufficiency.

71. Had Defendants adequately tested the safety of gadolinium-based contrast agents for use by consumers with renal insufficiency and disclosed those results to the medical community or the public, Plaintiff Sharon L. Herda would not have been administered gadolinium-based contrast agents.

72. As a direct proximate result of Defendants' failure to adequately test the safety of gadolinium-based contrast agents and as a direct and proximate result of Plaintiff Sharon L. Herda being administered gadolinium-based contrast agents as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff Sharon L. Herda has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory and punitive damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT V
NEGLIGENCE –
HIGHEST POSSIBLE DUTY OF CARE

73. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

74. Because gadolinium is highly toxic and inherently dangerous and ultra hazardous to humans, Defendants had a duty to exercise the highest possible degree of care in the design, manufacture, sale and/or distribution of gadolinium-based contrast agents into the stream of commerce, including the duty assure that their products did not pose a significantly increased risk of bodily harm and adverse events to persons exposed thereto.

75. Defendants failed to exercise the highest possible degree of care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution of gadolinium-based contrast agents into interstate commerce in that Defendants knew or should have known that the product was inherently dangerous and ultra hazardous to humans and caused such significant bodily harm or death and was not safe for administration to consumers.

76. Defendants also failed to exercise the highest possible degree of care in the labeling of gadolinium-based contrast agents and failed to issue to consumers and/or their health care providers' adequate warnings of the risks of serious bodily injury or death due to the use of a gadolinium-based contrast agents.

77. Despite the fact that Defendants knew or should have known that gadolinium-based contrast agents posed a serious risk of bodily harm to consumers and was inherently dangerous or ultra hazardous to humans, and particularly those with renal insufficiency, Defendants continued to manufacture and market gadolinium-based

contrast agents for administration to magnetic resonance imaging (MRI), magnetic resonance arteriography (MRA), and other radiological and diagnostic exams to patients with renal insufficiency.

78. Defendants knew or should have known that consumers such as Plaintiff Sharon L. Herda would foreseeably suffer injury as a result of Defendants' failure to exercise the highest possible degree of care as described above.

79. As a direct and proximate result of Defendants' negligence, Plaintiff Sharon L. Herda suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory and punitive damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT VI
NEGLIGENCE

80. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

81. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of gadolinium-based contrast agents into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk and adverse events.

82. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution of gadolinium-based contrast agents into interstate commerce in that

Defendants knew or should have known that the products caused such significant bodily harm or death and was not safe for administration to consumers.

83. Defendants also failed to exercise ordinary care in the labeling of gadolinium-based contrast agents and failed to issue to consumers and/or their health care providers' adequate warnings of the risk of serious bodily injury or death due to the use of gadolinium-based contrast agents.

84. Despite the fact that Defendants knew or should have known that gadolinium-based contrast agents posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market gadolinium-based contrast agents for administration in persons with renal insufficiency.

85. Defendants knew or should have known that consumers such as Plaintiff Sharon L. Herda would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

86. As a direct and proximate result of Defendants' negligence, Plaintiff Sharon L. Herda suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT VII
BREACH OF EXPRESS WARRANTY

87. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

88. Defendants expressly warranted that gadolinium-based contrast agents were a safe and effective paramagnetic contrast agent for use in magnetic resonance imaging and other radiological and diagnostic exams.

89. The gadolinium-based contrast agents manufactured and sold by Defendants did not conform to these express representations. The agents caused serious injury to consumers when administered in recommended dosages and in the manner directed by the Defendants.

90. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Sharon L. Herda suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of actual, statutory, and compensatory damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT VIII
BREACH OF IMPLIED WARRANTY

91. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

92. At the time Defendants designed, manufactured, marketed, sold, and distributed gadolinium-based contrast agents, Defendants knew of the use for which gadolinium-based contrast agents were intended and impliedly warranted the products to be of merchantable quality and safe for such use.

93. Plaintiff Sharon L. Herda and her healthcare providers reasonably relied upon the

skill and judgment of Defendants as to whether gadolinium-based contrast agents were of merchantable quality and safe for their intended use.

94. Contrary to such implied warranties, gadolinium-based contrast agents were not of merchantable quality or safe for their intended use because the products were unreasonably dangerous as described above.

95. As a direct and proximate result of Defendants' breaches of warranties, Plaintiff Sharon L. Herda suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of actual, statutory, and compensatory damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT IX
FRAUD / MISREPRESENTATION

96. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

97. Defendants knowingly and intentionally made material and false and misleading representations to Plaintiffs, their physicians and to the public that gadolinium-based contrast agents were safe for use and intentionally and knowing failed to disclose risks in the labeling, marketing and of the products.

98. Defendants' representations were in fact false. Gadolinium-based contrast agents were not safe for use, and their labeling, marketing and promotion did not fully describe all known risks of the products.

99. Defendants had actual knowledge of the defective nature of the products, the dangerous propensities of those products, and the unreasonable risks associated with their gadolinium-based contrast agents, or should have known such information, based upon studies, published reports and clinical experience, and information made available to them by persons in the scientific community.

100. Defendants knowingly and intentionally omitted this information in their product labeling, marketing, and promotion and instead, labeled, promoted and marketed their product as safe for use in order to avoid monetary losses and in order to sustain profits in their sales to consumers.

101. When Defendants made these representations that gadolinium-based contrast agents were safe for use, they knowingly and intentionally concealed and withheld from Plaintiffs their physicians and the public the true facts that gadolinium-based contrast agents were not safe for use in consumers with renal insufficiency.

102. Defendants had a duty to disclose to the end users, including Plaintiff Sharon L. Herda, their physicians and the public that gadolinium-based contrast agents were not safe for use in patients with renal insufficiency in that use under such circumstances posed a greater risk of the end users developing NSF/NFD or other serious injuries or death. Defendants duty to so disclose was based upon their superior knowledge of the dangers associated with their products, information which was material to Plaintiff Sharon L. Herda and her physicians' decision to use gadolinium-based contrast agents.

103. Plaintiff Sharon L. Herda and her physicians reasonably and justifiably relied on the Defendants' concealment of the true facts and reasonably and justifiably relied upon Defendants' representations to Plaintiff Sharon L. Herda and/or her health care providers

that gadolinium-based contrast agents were safe for human consumption and/or use and that Defendants' labeling, marketing and promotion fully described all known risks of the product.

104. Had Plaintiff Sharon L. Herda and her physicians known of Defendants' concealment of the true facts that gadolinium-based contrast agents were not safe for human use, Plaintiff Sharon L. Herda would not have been administered gadolinium-based contrast agents.

105. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff Sharon L. Herda was administered gadolinium-based contrast agents and suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory and punitive damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT X
NEGLIGENT MISREPRESENTATION

106. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

107. Defendants, in the course of their business profession, supplied Plaintiff Sharon L. Herda and her physicians with false information for guidance in their decision to use gadolinium-based contrast agents.

108. The false information supplied by Defendants to Plaintiff Sharon L. Herda and her physicians was that gadolinium-based contrast agents were safe and would not

adversely affect end users, such as Plaintiff Sharon L. Herda.

109. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff Sharon L. Herda and her physicians.

110. The false information obtained and communicated by Defendants to Plaintiff Sharon L. Herda and her physicians was material and they justifiably relied in good faith in the information to their detriment.

111. As a result of the negligent misrepresentations of Defendants, Plaintiff Sharon L. Herda suffered injuries, damages and losses as alleged herein.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory damages, as a jury deems just and reasonable, together with the costs of these proceedings.

COUNT XI
CAUSE OF ACTION
OUTRAGEOUS CONDUCT

112. Plaintiff Sharon L. Herda hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as set forth in this Count as follows:

113. Defendants' concealment from Plaintiff Sharon L. Herda and her physicians that gadolinium-based contrast agents are safe for use was extreme and outrageous conduct in that such conduct is so outrageous in character and so extreme in degree that it goes beyond all possible bounds of decency and is atrocious and utterly intolerable in a civilized community.

114. As a direct and proximate result of Defendants' extreme and outrageous conduct, Plaintiff Sharon L. Herda suffered severe emotional distress.

115. As a result of Defendants' outrageous conduct, Plaintiff Sharon L. Herda suffered injuries, damages and losses as alleged herein.

WHEREFORE, Plaintiff Sharon L. Herda demands a judgment against the Defendants, jointly and severally, in the form of compensatory and punitive damages, as a jury deems just and reasonable, together with the costs of these proceedings.

ADDITIONAL PRAYER FOR RELIEF

WHEREFORE, Plaintiff Sharon L. Herda additionally prays for the following relief:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2. Medical expenses, loss of income, and other economic damages in an amount to be determined at trial of this action;

3. Punitive damages to the extent permitted by law for the conscious, intentional, willful, wanton, reckless, fraudulent and inappropriate acts and conduct of the Defendants, done with total disregard for the rights and safety of those persons who used their products, including Plaintiff Sharon L. Herda.

4. Pre- and post-judgment interest;

5. Attorneys' fees, expenses, and costs of this action as allowed by law; and

6. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Procedure, Plaintiff hereby requests a trial by jury on all claims and issues so triable.

Respectfully submitted this 21st day of April, 2010.

/s/ W. Roger Smith, III
ANDY D. BIRCHFIELD, JR. (BIR006)
W. ROGER SMITH, III (SMI257)
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